

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sudhir V. Shah
Application No.: 10/731,522 Group Art Unit: 1654
Filed: December 9, 2003 Examiner: Winston, Randall O.
Confirmation No.: 3719

DIAGNOSIS AND TREATMENT OF HUMAN KIDNEY DISEASES



CERTIFICATE OF MAILING OR TRANSMISSION	
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Jennifer Warner Typed or printed name of person signing certificate	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☒ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

06/18/2004 CCHAU1 00000189 10731522 180.00 0P
01 FC:1806

SUPPLEMENTAL INFORMATION DISCLOSURE
CITATION IN AN APPLICATION

June 15, 2004

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2629.1003-009APPLICATION NO.
10/731,522FIRST NAMED INVENTOR
Sudhir V. ShahFILING DATE
December 9, 2003EXAMINER
Randall O. WinstonCONFIRMATION NO.
3719GROUP
1654

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE	5,091,180	02-25-92	Walker et al.
	AF	6,206,849 B1	03-27-2001	Martin et al.
	AG	6,383,817 B2	05-07-2002	Schwartz
	AH	6,589,966 B1	07-08-2003	Torti et al.
	AI	6,706,287 B2	03-16-2004	Ranganathan et al.

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AP	WO 00/54784	Aripkhozhaeva		X
	AQ	JP 05000949 A	Santen Pharmaceuticals Co., Ltd Dai Ichi Seiyaku Co., Ltd.	X (Abstract)	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AS4	Walker, P.D., et al., "Evidence Suggesting a Role for Hydroxyl Radical in Gentamicin-Induced Acute Renal Failure in Rats," <i>J Clin Invest</i> 81:334-341 (1988).
AT4	Shah, S.V., et al., "Evidence Suggesting a Role for Hydroxyl Radical in Glycerol-Induced Acute Renal Failure," <i>Am J Physiol</i> 255, (Renal Fluid Electrolyte Physiol. 24):F438-F443 (1988).
AU4	Baliga, R., et al., "Increase in Bleomycin-Detectable Iron in Ischaemia/Reperfusion Injury to Rat Kidneys," <i>Biochem J</i> 291(3):901-905 (1993).
AV4	Kontoghiorghese, G.J., et al., "Studies of Aluminium Mobilization in Renal Dialysis Patients Using the Oral Chelator 1,2-Dimethyl-3-hydroxypyrid-4-one," <i>Arzneim-Forsch/Drug Res.</i> 44(1):522-526 (1994).
AW4	Baliga, R., et al., "Oxidant Mechanisms in Toxic Acute Renal Failure," <i>Drug Metabolism Reviews</i> 31(4):971-991 (1999).
AX4	Walker, P.D., et al., "Gentamicin Enhanced Production of Hydrogen Peroxide by Renal Cortical Mitochondria," <i>Am J Physiol</i> 253:C495-C499 (1987).
AY4	Walker, P.D., et al., "Hydrogen Peroxide Cytotoxicity in LLC-PK ₁ Cells: A Role for Iron," <i>Kidney Int</i> 40:891-898 (1991).

EXAMINER

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AZ4	Abul-Ezz, S.R., <i>et al.</i> , "Role of Glutathione in an Animal Model of Myoglobinuric Acute Renal Failure," <i>Proc Natl Acad Sci</i> 88:9833-9837 (1991).
AR5	Ueda, N., <i>et al.</i> , "Gentamicin-Induced Mobilization of Iron from Renal Cortical Mitochondria," <i>Am J Physiol</i> 265(3 Pt. 2):F435-F439 (1993).
AS5	Baliga, R., <i>et al.</i> , "Evidence for Cytochrome P-450 as a Source of Catalytic Iron in Myoglobinuric Acute Renal Failure," <i>Kidney Int</i> 49:362-369 (1996).
AT5	Baliga, R., <i>et al.</i> , "Role of Cytochrome P-450 as a Source of Catalytic Iron in Cisplatin-Induced Nephrotoxicity," <i>Kidney Int</i> 54:1562-1569 (1998).
AU5	Hanss, B.G., <i>et al.</i> , "The Iron Chelator Deferoxamine Prevents Contrast Media Induced Acute Renal Failure in the Rabbit." Presented at the American Society of Nephrology, 23 rd Annual Meeting, <i>JASN</i> 1(4):612 (1990) (abstract).
AV5	Baliga, R., <i>et al.</i> , "Role of Iron in Cisplatin-Induced Acute Renal Failure in Rats," <i>J Am Soc Nephrol</i> 7(9):1822 (1996) (abstract).
AW5	Fernández-Real, J.M., <i>et al.</i> , "Cross-Talk Between Iron Metabolism and Diabetes," <i>Diabetes</i> , 51:2348-2354, 2002
AX5	Nitenberg, A., <i>et al.</i> , "Coronary Microvascular Adaptation to Myocardial Metabolic Demand Can Be Restored by Inhibition of Iron-Catalyzed Formation of Oxygen Free Radicals in Type 2 Diabetic Patients," <i>Diabetes</i> , 51:813-818, 2002

EXAMINER

DATE CONSIDERED

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references (AP, AQ, AW5, AX5) are enclosed.
 - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/553,496, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
 - ☒ Previously cited references (AL-AO, AY3, AZ3, AR4) were cited in the enclosed International Search Report in a related foreign application.
 - ☒ The "concise explanation" requirement (non-English references) for reference AQ under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☒ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 10/820,478, by Sudhir V. Shah, filed April 8, 2004, Docket No.: 2629.1003-008

____ U.S. Patent Application No. 10/731,521, by Sudhir V. Shah, filed December 9, 2003, Docket No.: 2629.1003-010

____ U.S. Patent Application No. 10/820,537, by Sudhir V. Shah, filed April 8, 2004, Docket No.: 2629.1003-011

Examiner

Date

- [X] A copy of each above-cited application, including the current claims, is enclosed.
- [] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [X] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated: June 15, 2004